



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-0600]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis Drug Susceptibility Testing (OMB Control No. 0920-0600, Expires 5/31/2016) - Extension - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As part of the continuing effort to support domestic public health objectives for treatment of tuberculosis (TB), prevention of multi- drug resistance, and surveillance programs, CDC is requesting approval for an extension of three years from the Office of Management and Budget to continue information collection from participants in the Model Performance Evaluation Program for Mycobacterium tuberculosis Susceptibility Testing. Extension of this information collection will not require changes in the scope of the study, methodology, information collection instruments, or burden on the respondents.

While the overall number of cases of TB in the U.S. has decreased, rates still remain high among foreign-born persons, prisoners, homeless populations, and individuals infected with HIV in major metropolitan areas. To reach the goal of eliminating TB, the Model Performance Evaluation Program for Mycobacterium Tuberculosis Drug Susceptibility Testing is used to monitor and evaluate performance and practices among national laboratories performing M. tuberculosis susceptibility testing. Participation in this program is one way laboratories can ensure high-quality laboratory testing, resulting in accurate and reliable testing results.

Extension of this information collection provides CDC with an evaluation program to assess the ability of the laboratories

to test for drug resistant M. tuberculosis strains. Laboratories also have a self-assessment tool to aid in optimizing their skills in susceptibility testing. The information obtained from the laboratories on susceptibility practices and procedures is used to establish variables related to good performance, assessing training needs, and aid with the development of practice standards.

Participants in this program include domestic clinical and public health laboratories. Data collection from laboratory participants occurs twice per year. The data collected in this program will include the susceptibility test results of primary and secondary drugs, drug concentrations, and test methods performed by laboratories on a set of performance evaluation (PE) samples. The PE samples are sent to participants twice a year. Participants also report demographic data such as laboratory type and the number of tests performed annually.

There is no cost to respondents to participate other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Domestic Laboratory	Participant Biosafety Compliance	93	2	5/60

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
	Letter of Agreement			
	MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet	93	2	30/60
	Online Survey Instrument	93	2	15/60

Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

[FR Doc. 2016-02519 Filed: 2/8/2016 8:45 am; Publication Date: 2/9/2016]